INDEX

	Page
Opinion below	1
Jurisdiction	2
Questions presented	2
Statute involved	4
Statement	5
Argument	18
Conclusion	28

CITATIONS

Cases:

American Airlines, et al. v. *Civil Aeronautics Board*, 192 F. 2d 417	24
Anniston Mfg. Co. v. *Davis*, 301 U.S. 337	21
Buttfield v. *Stranahan*, 192 U.S. 470	20
Federal Security Administrator v. *Quaker Oats Company*, 318 U.S. 218	19, 23, 24
Interstate Commerce Commission v. *Jersey City*, 322 U.S. 503	27
Lichter v. *United States*, 334 U.S. 742	20
Market Street Ry. Co. v. *Railroad Commission*, 324 U.S. 548	25
National Labor Relations Board v. *Donnelly Garment Co.*, 330 U.S. 219	28
National Labor Relations Board v. *Pittsburgh S.S. Co.*, 340 U.S. 498	25
62 Cases of Jam v. *United States*, 340 U.S. 593	19
Universal Camera Corp. v. *National Labor Relations Board*, 340 U.S. 474	25, 26
Wong Yang Sung v. *McGrath*, 339 U.S. 33	22

Statutes:

Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040; 21 U.S.C. 301:	
Sec. 401 (21 U.S.C. 341)	4, 20
Sec. 402(a), 21 U.S.C. 342(a)	23
Sec. 402(b), 21 U.S.C. 342(b)	23
Sec. 403(g) [21 U.S.C. 343(g)]	5
Sec. 505, 21 U.S.C. 355	22
Sec. 701(e), 21 U.S.C. 371(e)	4
Sec. 701(f), 21 U.S.C. 371(f)	4, 26

Misc.:

Dunn, *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record*, 1316-1327	22
H. Rep. No. 2139, 75th Cong., 3d Sess., 2	23
H. Rep. No. 2356, 82d Cong., 2d Sess., 24	22
S. Res. 194, 75th Cong., 2d Sess., Dunn, pp. 1316-1327	22

In the Supreme Court of the United States

OCTOBER TERM, 1952

No. 584

GLYCO PRODUCTS CO., INC., PETITIONER

v.

FEDERAL SECURITY ADMINISTRATOR

No. 610

ATLAS POWDER COMPANY, A CORPORATION, PETITIONER

v.

OSCAR R. EWING, FEDERAL SECURITY ADMINISTRATOR

ON PETITIONS FOR WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Glyco R. 757 and Atlas R. 3283) is reported at 201 F. 2d 347. The administrative order under review (Glyco R.

700-746 and Atlas R. 458-475) was published at 17 F. R. 4453. Respondent's memorandum denying Atlas Powder Company's motion to reopen the record (Atlas R. 476-484) was published at 17 F. R. 4467.

JURISDICTION

The judgment of the Court of Appeals was entered December 22, 1952 (Glyco R. 773 and Atlas R. 3299). Atlas Powder Company's petition for rehearing was denied January 14, 1953 (Atlas R. 3299). Glyco Products Company filed its petition for a writ of certiorari on February 4, 1953. Atlas Powder Company filed its petition on February 17, 1953. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1) and Section 701(f)(4) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1055, 21 U.S.C. 371(f)(4).

QUESTIONS PRESENTED

1. Whether the Federal Security Administrator, in establishing a standard of identity for bread to "promote honesty and fair dealing in the interest of consumers", was required to authorize, and was without authority to forbid, the use of polyoxyethylene monostearate, a synthetic chemical bread softener, which he found on substantial evidence—

(a) contains residues of known poisonous glycols;

(b) is a reaction product of variable and uncertain chemical composition, not a chemical entity, containing some polyoxyethylene glycol esters of low and high molecular weights

known to be poisonous to experimental animals;

(c) has no history of long use in food from which its safety could be appraised;

(d) has been improperly and insufficiently tested by pharmacological and related methods to establish scientifically whether it is safe for the use proposed;

(e) has an unknown metabolic fate in the animal and human body after ingestion;

(f) may be responsible for causing urinary calculi observed in bladders taken from experimental animals;

(g) may increase the susceptibility of animals to infectious disease organisms ingested with food; and

(h) serves no useful purpose in bread, but, on the contrary, gives bread a deceptive artifical softness enabling bakers to sell old bread as fresh bread.

2. Whether, despite such evidence and findings as a basis for the exclusion of polyoxyethylene monostearate, the Administrator nevertheless was compelled to permit its use because he permitted use of another class of surface active agents (mono- and diglycerides) which he found significantly different, in that the use of the latter could be so limited in amounts as to avoid deceptive bread softening while preserving their advantages as shortening.

3. Whether the Administrator, in the first instance, and the Court of Appeals, on review, abused their discretion in refusing to reopen the record

when each concluded independently that the several tenders of alleged new evidence by Atlas, including a tender of evidence said by Atlas to be in the Administrator's possession, would not change the result because all such evidence was incomplete and indecisive on the safety issue.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040; 21 U.S.C. 301 *et seq.*, in pertinent part, provides:

> Sec. 401 [21 U.S.C. 341]. Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity * * * In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. * * *

The regulations may be promulgated only after public proceedings and must be based on a record made at a hearing. Sec. 701(e), 21 U.S.C. 371(e). Judicial review of the regulations is permitted under Section 701(f), 21 U.S.C. 371(f).

After a standard of identity has been established, a food that fails to comply is declared to be misbranded.

> Sec. 403 [21 U.S.C. 343]. A food shall be deemed to be misbranded—
>
> (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavorings, and coloring) present in such food.

STATEMENT

Petitioners are attacking a rule-making order of the Federal Security Administrator by which he established a standard of identity for bread. They will be adversely affected because in the future the order will not permit bakers—petitioners' customers—to use polyoxyethylene monostearate as a bread softener.

The administrative proceeding, after an interruption due to the war, was reopened in 1948 for taking evidence of new developments in baking technology (Atlas R. 1-4). The principal of these was the introduction in early 1947 of polyoxyethylene monostearate to make bread softer to the touch over a period of days and thus to appeal to

the large segment of the public which judges bread freshness by squeezing the wrapped loaf.

The reopened hearing lasted 116 days, ending September 20, 1949. More than 160 witnesses testified; the record grew to 17,000 pages; more than 500 exhibits were received Most of this evidence related to the chemical bread softeners.

Atlas Powder Company produces polyoxyethylene monostearate—trade name Myrj 45—by the direct reaction of ethylene oxide with commercial stearic acid in a theoretical proportion of eight molecules of ethylene oxide to one molecule of stearic acid (Atlas R. 3205). The competing Glyco product—trade name Sta-Soft—is produced by first reacting ethylene oxide with water, ethylene glycol, or diethylene glycol to form polyoxyethylene glycol which is then reacted with stearic acid (Atlas R. 1394-1395, 1447, 1451, 1500) . Neither Myrj 45 nor Sta-Soft is a chemical entity (Atlas R. 729, 1538-1539). The products, despite the different methods of production, are substantially alike (Atlas R. 1463, 1516, 1824, 2057-2058, 2059, 3205-3206, Ex. 95).

Before the introduction of the chemical softeners into the bread supply, polyoxyethylene glycols had been used as commercial chemicals in plastics, insecticides, antifreezes, polishes, etc., but were not used in foods (Ex. 100, pp. 2, 4, 10, Ex. 102, pp. 12-15, 67-78). In late 1946 or early 1947, cereal chemists employed by R. T. Vanderbilt Company discovered that polyoxyethylene monostearate had a softening effect on bread (Atlas R. 725-726,

2855, Ex. 58).[1] They promptly offered it to bakers for commercial use (Atlas R. 2855, 2882).

The American Institute of Baking, the scientific and educational organization of the industry (Atlas R. 532), soon thereafter issued a bulletin cautioning bakers against using the chemical (Atlas R. 697-698). Bakers were told that the active ingredient belonged to a group of chemical compounds, some of which are notoriously poisonous, and that satisfactory evidence of harmlessness had not been made available.[2] The Food and Drug Administration also questioned the safety of the softener (Atlas R. 3083). Nevertheless, many bakers began to use it (Atlas R. 692), largely because of competition from softer loaves (Atlas R. 3000, 3005, 3011, 3016, 3036, 3063, 3084, 3087).

The notice of reopening the hearing, published in October 1948, included a proposed regulation which did not permit use of the softeners. At the hearing, neither the American Bakers Association, composed primarily of wholesale bakers, nor the Retail Bakers Association advocated or presented evidence to support their use. The burden of establishing that use of polyoxyethylene monostearate in bread would be consistent with the promo-

---

[1] Atlas asserts that its product is an emulsifier (No. 610, Pet. 3). Its own witness testified that the Company has never been able to demonstrate whether Myrj 45 functions as an emulsifier (Atlas R. 753). Unlike mono- and diglycerides, its action in bread dough is independent of the shortening used (Atlas R. 674-675, 753).

[2] The only evidence of safety in Atlas' possession at that time was some preliminary tests done by Dr. John C. Krantz, which he admitted were inadequate to justify use of Myrj 45 in bread (Atlas R. 847-848, 3173-3174).

tion of honesty and fair dealing in the interest of consumers thus fell upon Atlas Powder Company and Glyco Products Company, primary manufacturers, and R. T. Vanderbilt Company and C. J. Patterson Company, distributors of Myrj 45 and Sta-Soft.[3] To do this, they undertook to explain the chemical composition of the softener, to prove that polyoxyethylene monostearate[4] serves a useful function in bread, and that its safety had been established through pharmacological testing with small laboratory animals,[5] through experiments to determine its metabolic fate,[6] and by feeding it

---

[3] Under Section 7(c) of the Administrative Procedure Act, 5 U. S. C. 1006 (c), the Food and Drug Administration had the general burden of supporting the regulations. But other parties who were proponents of a different regulation from that proposed also had a burden to maintain for that purpose. Sen. Rep. No. 752, 79th Cong., 1st Sess. (1945), Administrative Procedure Act, Legislative History, Sen. Doc. No. 248, 79th Cong., 2d Sess., 208 (1944-1946).

[4] Atlas proposed before the Administrator that he permit all of its Spans, Tweens, and Myrjs. Its chief chemist, Dr. Rose, recommended an amendment which would cover its entire line (Atlas R. 711-712, 713-716, 717-720, 723-725). In each group of Spans, Tweens, and Myrjs, a myriad of different compounds was possible (Atlas R. 729-732), including many that had never been studied (Atlas R. 732).

[5] In studying the toxic potential of a substance like polyoxyethylene monostearate, it is standard practice to conduct both acute and long term feeding tests with small laboratory animals. To give the chronic test validity, it is necessary that the experiment be conducted with test animals and control animals. These are selected so as to make the two groups as nearly identical as possible at the start of the test. During the test, the animals' diet and living conditions are identical except that the diet of the test group contains the material being studied. Any differences between the test animals and the controls, theoretically at least, are due to the material under study.

[6] This was a study in which the excretions of test animals and some human patients were examined to determine whether the body promptly eliminated the non-food part of polyoxyethylene monostearate. The compound is about 40% stearic

to a few people under the care of a physician where they could be observed for symptoms of harm.[7]

All of the evidence offered by the proponents was critically cross-examined. Many defects in the safety testing were developed.[8] In addition, Swift & Company and the Institute of Shortening and Edible Oils, Inc., presented two scientists, Dr. Anton J. Carlson, the physiologist, and Dr. Robert S. Harris, M.I.T. nutritionist, both of whom expressed expert opinions that the Atlas and Glyco showing as to safety was inadequate (Atlas R. 2913-2915, 2936, 2951-2962).

Expert witnesses representing the Council on Foods and Nutrition of the American Medical Association (Atlas R. 2832-2850) and the Food and Nutrition Board of the National Research Council (Atlas R. 2900-2901) offered resolutions adopted by these scientific groups urging that the softeners should not be permitted in bread until their safety was shown beyond doubt. The Council on Foods and Nutrition, which had reviewed the Atlas scientific work (Atlas R. 2841-2842), stated (Atlas R. 2845-2846):

> Available knowledge of the possible toxicity of these substances [Atlas products] is fragmentary—particularly is evidence lacking as to chronic toxicity. The employment of these

---

acid, which would be utilized as food and about 60% "polyol", which is non-food.

[7] The longest controlled human feeding test with Myrj 45 lasted about one month (Atlas R. 1212) and only 3 people under any observation at all had taken it for more than 6 months (Atlas R. 1244). The longest feeding was 11 months (Atlas R. 1191).

[8] See for example footnote 12 *infra*, pp. 14-15.

> agents in * * * bread * * * could lead to the ingestion of considerable quantities of these materials of uncertain toxicological action.

As to functional use, there was conflicting evidence whether polyoxyethylene monostearate affected bread softness only or whether it arrested the process of staling (Atlas R. 539, 550, 552-559, 562, 569-570, 735-736, 742, 3082, 3089, Ex. 58), and whether the softener improved or adversely affected bread quality (Atlas R. 537-539, 2785, 2811, 2880, 2903, 2992, 2998-2999, 3005-3006, 3015, 3029, 3037, 3044-3045, 3049, 3053-3054, 3058, 3064).

Practically all of the bakers testified, however, (1) that the public confuses softness with freshness in purchasing bread (Atlas R. 2798-2799, 2807-2808, 2818, 2829, 2899, 2903, 3005, 3012, 3019, 3031, 3038, 3059), (2) that the use of softeners would enable them to leave bread on the retail shelves longer and thus sell old bread as fresh bread (Atlas R. 2084, 2798, 2887, 2895, 3006-3007, 3050, 3056, 3060), and (3) that the softeners would facilitate "bread rolling", i.e., where old bread is taken from one retail outlet and left at another as fresh bread (Atlas R. 2091, 2904-2905, 2994, 3017-3019, 3041, 3045-3046, 3064).

The Administrator issued a tentative order on August 8, 1950 (Atlas R. 5-16), which did not permit polyoxyethylene monostearate or the other Atlas products proposed. Detailed findings of fact were made which, in summary, were that the

bread softeners were deceptive as to the age of bread and that the scientific investigational work had not definitely established their safety.

Atlas Powder Company (Atlas R. 47-108) and Glyco Products Company (Glyco R. 1-23) excepted to the findings and order. Atlas also filed a motion to reopen the record so that it might show that mono- and diglycerides have the same softening effect as polyoxyethylene monostearate and that the evidence available as to safety of the mono- and diglycerides was no more convincing (Atlas R. 24-39). It was argued that because the use of glycerides was permitted Atlas' products likewise should be permitted (See Atlas R. 384).

On February 2, 1951 (Atlas R. 129) Atlas proposed that all available scientific data be submitted to the newly organized Food Protection Committee of the National Research Council for expert appraisal.[9] The proposal stated that "the results would make it possible for the Federal Security Agency to issue a final order based on impartial scientific opinion, as opposed to opinion which may be colored by the bias and interest of individual manufacturers" (Atlas R. 132). All of the data on safety in this record, together with new experiments, were submitted to the Committee by

---

[9] The National Research Council is a highly reputable scientific organization with semi-official status. It represents "the very foremost in scientific thinking in the United States" (Atlas R. 1014). The Food Protection Committee was created by the National Research Council to aid industry and Government in evaluating the pharmacological properties of chemicals which might find their way into foods.

Atlas prior to June 11, 1951 (Atlas R. 144-148). The Food Protection Committee on that date issued a statement finding that the Atlas evidence was insufficient to show safety (Atlas R. 169-170). The Committee, referring to the Atlas products as "esters of non-glycerol alcohols", concluded that the experiments had not been properly planned to delineate the toxic potentials of the products and that knowledge of their metabolic fate and possible toxicological effects was insufficient.

When the results of the Committee's study were unfavorable to the Atlas compounds, Atlas began to file with the Administrator opposing memoranda (Atlas R. 277, 389, 412-435). In addition, it outlined an extensive program of planned research (Atlas R. 284-299) which, it estimated, would be completed by September 1, 1953 (Atlas R. 271, 299).[10]

On May 12, 1952, the Administrator issued the final order (Atlas R. 458-475).

The Administrator found, on the deception issue, (1) that polyoxyethylene monostearate enables bakers to prepare bread that stays softer to squeezing over a period of days, (2) that softness is the only characteristic of freshness affected by the

[10] In a letter dated December 4, 1951, Atlas referred to certain experiments underway in the Food and Drug Administration, contending that they would be completed in the winter of 1951-1952 and results evaluated by the summer of 1952 (Atlas R. 347). It contended that if these tests were favorable to Atlas, the two-year period it had referred to could be cut down (Atlas R. 350). The Food and Drug Administration's tests are still incomplete (Atlas Reply Brief in Court of Appeals, p. 8a).

chemical, (3) that this artificially created softness enables bakers to appeal to consumers who select bread by feel, thinking the softness to be an indication of freshness, and (4) that this has deceived, and does deceive, the purchaser as to the age of the bread and facilitates the undesirable distribution practice of "bread rolling" (Finding 39, Atlas R. 463-466). He found, in conclusion, that consumers will receive no significant benefits from the use of Atlas type bread softeners and may be deceived by them (Finding 42, Atlas R. 472).

On the question of safety, the Administrator found that polyoxyethylene monostearate softeners were first introduced into the bread supply in 1947 (Finding 39, Atlas R. 463-465). They are of variable chemical composition and are known to contain poisonous glycols (Finding 40, Atlas R. 467-468).[11] The laboratory animal work reported showed injuries when the materials were fed in amounts of 10% or more of the diet, but when lesser amounts were fed the evidence of injury was not clear. The Administrator found fundamental defects in the animal experiments, which he specified. Only one

---

[11] It was clear that the softeners contain small residues of ethylene and diethylene glycol (Atlas R. 1400, 1402, 1406, 1428, 1434, 1442, 1502, 1507, 1529, 1611, 1616-1617, 1663-1673a, 1953, 2019, Ex. 97 and 99), chemicals known to have significant chronic toxicity (Exs. 212, 350-354). Myrj 45 and Sta-Soft contain as well other glycol esters of varying molecular weights (Atlas R. 729, 1416, 1462, 1470, 1473-1474, 1536, 1548, Ex. 101) including some of high and some of low molecular weights which cause injury when fed to test animals (Atlas R. 726, 1550, 1558-1561, 1636, 1642, 1645, 1714, 1721-1722, 1779). The exact amount of these deleterious substances present is unknown.

level of dosage was fed, which was not high enough to delineate the toxic potentials. Animals of only one sex were used. The number of animals was not great enough to permit sound conclusions to be drawn. The causes of certain observed deleterious effects were not properly investigated. The Administrator disagreed with the Atlas witnesses that the observed differences in growth rate, mortality, and pathology between control and test animals could be disregarded as "unimportant, not significant, or not connected with the feeding of the test substances" (Finding 41, Atlas R. 469-471).[12]

---

[12] Myrj 45 was tested on rats, rabbits, monkeys and dogs (Ex. 61 pp. 1-60). In the course of the life span study with two groups of 15 rats each, more than one-half of the animals died prematurely (Atlas R. 891) and at the end of the period there were 5 survivors in the control group but only 2 survivors in the test group (Atlas R. 891). This made it impossible to prepare meaningful growth charts for Myrj animals (Atlas R. 893). Two monkeys were studied, but one of these died of tuberculosis during the test (Ex. 61, pp. 6-7). Both monkeys lost weight. An experiment was started with five test and five control rabbits (Atlas R. 808). The experiment was stopped at 19 weeks because only one rabbit in the test group survived, the other four having been the victims of cannibalism (Ex. 61, pp. 28-30). No such fate befell the control animals, but Dr. Krantz attached no significance to it (Atlas R. 890), despite the facts that he had never before encountered cannibalism in rabbits (Atlas R. 898) and that rabbits are known to be vegetarian animals (Atlas R. 1274) unlikely to eat each other. In the test conducted on two dogs, one died of an infection (Atlas R. 1007).

Another investigator tested Myrj 45 and Sta-Soft (Atlas R. 2261). He used rats, six rabbits, three dogs, and five humans (Atlas R. 2471). Most of the experiments were for 12 weeks (Atlas R. 2262-2269). On cross-examination he agreed that more work was needed to test the trends developed by his experiments (Atlas R. 2456, 2457-2460, 2480-2481, Exs. 152, 164). In his rat tests, he found abnormal liver pathology (Atlas R. 2270-2273, 2362), and some abnormalities of other organs (Atlas R. 3210-3211). He disregarded this because no "con-

On the question of the metabolic fate of the chemicals when ingested into the body, the Administrator found a disagreement among investigators.[13]

---

sistent" pathology was seen. Out of nine test animals, two had tumor growths (Atlas R. 3212). There were no such growths in the controls. There was a "slight" tendency for reproduction performance to diminish (Atlas R. 2386). He had an exceedingly high mortality rate (Atlas R. 2369). In one study, 80% of the test animals (males) died as against 20% of the controls; 60% of the test females died as against 0% for the controls (Atlas R. 2364-2365, see also Atlas R. 2368). The causes of the deaths were infections or causes "not specifically diagnosed" (Atlas R. 2366). But Dr. Oser "doubts" that any deaths were due to the test diet (Atlas R. 2276). Only 3 rats on Sta-Soft survived more than 80 weeks of the test (Ex. 357).

In his rabbit experiment, one animal developed coccidiosis (Atlas R. 2309). There were no controls, so Dr. Oser attributed the abnormal liver pathology to causes other than the test material (Atlas R. 2314-2316). There were blood deviations, but he thought these unimportant (Atlas R. 2310-2311). He admitted that so few animals were used that any deviations could be attributed to chance (Atlas R. 2416-2417).

Dr. Oser's dogs also had abnormal kidney pathology (Atlas R. 2320-2324) and abnormalities of the gastrointestinal tract, but this again was thought to be due to outside causes and not the test diet (Atlas R. 2323-2324).

See also Ex. 201, a report made to C. J. Patterson Co., showing severe injury to golden hamsters from Sta-Soft.

[13] The question of metabolic fate of the compounds was considered important in deciding their harmlessness (Atlas R. 1929-1930, 2938). There was a possibility that the polyol might be converted into oxalic acid, forming urinary bladder stones comparable to those known to occur from diethylene glycol (Atlas R. 1083, 2010). The experts were in general agreement that it would be an undesirable effect to have the non-food polyol stored in the body for indefinite periods (Atlas R. 1935, 1984, 2146, 2431). Atlas sought to prove that the polyol was rapidly excreted and thus that no harm could come from the compounds (Atlas R. 764-765, 777-778, 786-787).

Atlas' key witness was Dr. Culver (Atlas R. 1040), who did recovery studies on Tween 80 and Myrj 45. He concluded, from results of analyses not made by him but by Atlas' laboratories (Atlas R. 1083-1084, 1088, 1141), that the polyol was almost completely excreted. Using Tween 80 on 3 patients, he

The Administrator noted that the record suggested the possibility that the softener may increase the susceptibility of animals to infectious disease organisms taken in with the food, but that the evidence was inadequate to supply the answer whether the chemical actually had the effect or whether, if so, it would be significant in human infectious diseases (Finding 42, Atlas R. 472-473).[14]

Having pointed out the softener's potentialities for harmful effect, and having explained in detail the deficiencies in the evidence on the safety issue, the Administrator concluded that despite the absence of definite evidence of past injury from poly-

---

claimed 100% recovery of the polyol. One patient, however, did not give the same results (Atlas 1090). This was disregarded, because it did not "fit" with the other three patients. On Myrj 45, six patients were tried (Atlas 1103-1104). Here two did not give complete recoveries (Atlas 1103-1104). They too were disregarded, and Dr. Culver reached his conclusion on the four "well controlled" cases (Atlas R. 1104-1106).

Dr. Shaffer, Glyco's expert, studied the fate of polyoxyethylene glycols used in Sta-Soft. His recoveries were not complete (Atlas R. 1826-1840, 1944, 2011, 2019). He concluded that the polyol from Sta-Soft undergoes some change in the body that cannot be explained (Atlas R. 1837, 2060, 2076-2078).

[14] Dr. Rene DuBos, of the Rockefeller Institute for Medical Research (Atlas R. 3154-3156), discovered that Tween 80, Tween 60, G-2144 and G-2124 (Myrj type products) were among the few surface active agents of a great many tested that would affect the growth pattern of tubercle bacilli (Atlas R. 3156-3159). Without these wetting agents the bacilli grow only in clusters and only on the surface of the growth medium (Atlas R. 3159). With the agents, the growth pattern is drastically changed and the bacilli grow throughout the medium in small clumps or as isolated individuals (Atlas R. 3159).

Dr. DuBos said that additional work would have to be done to determine whether these materials would have an effect on the course of tuberculosis in man or other animals (Atlas R. 3163, 3165).

oxyethylene monostearate, it was impossible to find that "there is no likelihood of injury from bread containing these substances in the amounts proposed . . . [if eaten] over a life span". Finally, on the basis of the whole record, he expressed his conclusion that it would not promote honesty and fair dealing in the interest of consumers to recognize polyoxyethylene monostearate as an optional ingredient in bread (Finding 42, Atlas R. 472-473).

The Administrator also filed a memorandum explaining that Atlas Powder Company's motion to reopen the record was denied because the supplemental data submitted to support it revealed that the investigations to establish safety were still incomplete in important respects (Atlas R. 482-484). The memorandum also explained why mono- and diglycerides were considered in separate classes from the Atlas product (Atlas R. 478-482). Mono- and diglycerides are closely related to natural fats; they had been used in food for at least 20 years; and the record showed no questions raised concerning their safety. (Atlas R. 478-479).[15] In addition, the use of glycerides could be so limited as to avoid deceptive bread softening while preserving their advantage as shortening (Atlas R. 484).

On petitions for review filed by Atlas and Glyco in the Court of Appeals for the Third Circuit, the order establishing the regulations was unanimously

[15] The Administrator found that mono- and diglycerides are harmless, but that a final decision on their safety could not be made until the full significance of their surface-active effects had been explored along the lines suggested by the Food Protection Committee (Finding 5, Atlas R. 459-461).

affirmed. A careful review of the whole record convinced the court that "the Administrator properly concluded that the safety of the questioned products had not been established" (Atlas R. 3292). The negative finding in that respect, combined with the affirmative findings as to "the lack of long term experience with daily human consumption of these products", "their complex and not wholly clear chemistry", "the alarm with which that chemistry was viewed by competent and disinterested scientific groups and the actual presence of toxic material even in very small quantities", the court said, justified "their rejection as an item of daily human diet until satisfactory affirmative proof of safety should be forthcoming" (Atlas R. 3292).

ARGUMENT

1. a. Glyco Products Co. (petitioner in No. 584) contends that the order here involved, fixing the standard of identity for bread, is invalid for the reason that Section 401 does not authorize the Administrator to forbid the addition of optional ingredients which do not affect the economic integrity of the food as such, in this case the characteristic of bread as bread. (Pet. No. 584, 8-9), 11-19.)

Aside from the fact that, under petitioner's own interpretation of the statute, an ingredient which may be poisonous and which has been found to deceive the public as to freshness, obviously does affect the characteristic of bread as bread, there is no merit in the contention. As the court below

pointed out, this argument is refuted by the plain language of the statute, and by the decision of this Court in *Federal Security Administrator* v. *Quaker Oats Company,* 318 U.S. 218. The clear language of Section 401 empowers the Administrator to permit or not permit optional ingredients. And as this Court said in the *Quaker Oats* case, at p. 232:

> The statutory purpose to fix a definition of identity of an article of food sold under its common or usual name would be defeated if producers were free to add ingredients, however wholesome, which are not within the definition.

See also 62 *Cases of Jam* v. *United States,* 340 U. S. 593, 598, where the holding was restated, this Court saying of the *Quaker Oats* decision:

> We sustained the regulations, holding that Congress had constitutionally empowered the Administrator to define a food and had thereby precluded manufacturers—or courts—from determining for themselves whether some other ingredients would not produce as nutritious a product.

That decision answers as well Glyco's second contention (No. 584, Pet. 19-20) that Section 401 is an unlawful delegation of legislative authority. There is an unbroken line of decisions, extending throughout the entire history of our constitutional form of government, holding that the Constitution does not forbid Congress to delegate to an adminis-

trative agency the task of implementing legislation by filling in the details.[16]

In Section 401 Congress described the legislative objective—the promotion of honesty and fair dealing in the interest of consumers. Congress prescribed the method of achieving that objective—the fixing and establishing of reasonable definitions and standards of identity for any food, under its "common or usual name", including the specification of the permitted optional ingredients. And Congress delegated the task of fixing the standards to the Federal Security Administrator. Only recently this Court reaffirmed a long line of decisions holding that general terms such as "excess profits," "just and reasonable rates" and "public interest, convenience or necessity" were proper standards for delegated legislation. *Lichter* v. *United States*, 334 U. S. 742, 785, 786. We think it clear that Section 401 contains a sufficiently definite standard for administrative action.

b. Atlas Powder Company (No. 610, Pet. 3-4, 12) argues that the Administrator exceeded his authority in excluding polyoxyethylene monostearate on a purely negative finding that its safety had not been established (No. 610, Pet. 8-20).

The entire argument on this point, based on a single sentence in finding 42 (Atlas R. 473), ignores the whole of findings 40 and 41 and the con-

[16] It is clear that Congress may confer upon the executive branch the power to fix standards of a technical nature with respect to which a statute is to apply. See, for example, *Buttfield* v. *Stranahan*, 192 U. S. 470, where an administrative official was lawfully authorized to fix uniform standards of purity for imported tea.

text of finding 42 itself (Atlas R. 467-473). Actually, the Administrator made a series of affirmative findings that raised the gravest doubts about the safety of polyoxyethylene monostearate. Among these were the facts that the chemical contains residues of poisonous impurities, is closely related to known poisons, contains a non-food portion with an unknown metabolic fate in the human body, has no long standing food use indicating its safety, and has been inadequately tested in the laboratory to show whether it is safe. What the Administrator found on this record was that there were signs tending to show injury to the test animals, but that the experiments were so poorly planned and conducted that a "definite" scientific judgment could not be reached as to whether injury was attributable to the chemical.

The Court of Appeals painstakingly appraised all of the evidence. The court held that the exclusion of the chemical was not grounded alone on a negative finding, but that the "negative finding was given effect in the light of a number of significant facts" (Atlas R. 3292).[17]

Although conceding that the Administrator could bar a chemical from a standard of food if there were "an affirmative finding that its unsuit-

---

[17] Atlas contends that an "inherently impossible" burden was placed upon it, citing *Anniston Mfg. Co.* v. *Davis*, 301 U. S. 337, 352-354. But that case holds that "Impossibility of proof may not be assumed"; whether it exists must await until all the facts are in. The Administrator has specified the obvious defects in petitioner's safety evidence. It cannot now be said that it will be impossible to prove whether the chemical is safe.

ability has been proven," Atlas contends that it cannot be barred on any finding less affirmative (No. 610, Pet. 13-17). To bolster the point, the argument is made that because Congress enacted special provisions relating to the safety of new drugs (No. 610, Pet. 13-14),[18] and now has under consideration new legislation dealing with chemical additives to food (No. 610, Pet. 17-18),[19] the implication is that

---

[18] Petitioner in No. 610 (Pet. 13) implies that the new drug section and the food sections were studied together throughout the 5 year legislative history of the Act. The fact is the new drug provisions had their genesis in the Elixir Sulfanilamide tragedy which occurred in September and October 1937. Sen. Res. 194, 75th Cong., 2d Sess., called upon the Secretary of Agriculture for a full report. The report was submitted November 25, 1937. Dunn, *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record*, 1316-1327. The revision of the statute had been under consideration in Congress since 1933. The Federal Food, Drug, and Cosmetic Act, with the new drug provisions inserted in Section 505, was signed by the President on June 25, 1938.

This Section prohibits the interstate distribution of all new drugs before they have been adequately tested for safety. There is no comparable provision under the food chapter of the Act. Chemicals that have not been adequately tested for food use can be introduced into the food supply without advance clearance with the Administrator, as Atlas did. But this does not imply that the Administrator must disregard safety questions in carrying out the mandate of Section 401 to "promote honesty and fair dealing in the interest of consumers."

[19] See *Wong Yang Sung* v. *McGrath*, 339 U. S. 33, 47-48, where the Court refused to draw an inference from proposed legislation. But, in any event, a report of the House of Representatives Committee To Investigate the Use of Chemicals in Foods, stated: "Section 401 of the Federal Food, Drug, and Cosmetic Act authorizes the Federal Security Administrator to define and standardize foods for the purpose of promoting honesty and fair dealing in the interest of consumers. This empowers him to determine whether a chemical proposed for use in a standardized food has been demonstrated to be safe (H. Rep. No. 2356, 82d Cong., 2d Sess., 24).

no authority was given the Administrator by Section 401 to consider questions of safety.

It is obvious, however, that considerations of safety may enter into the Administrator's judgment; for "fair dealing" with the consumer requires protection of his health at least as much as protection of his pocketbook. If it is unfair to put before the consumer foods whose economic worth he cannot properly judge, it is certainly no less unfair to offer him foods whose safety neither he nor the best qualified scientists can judge.[20]

And once it is admitted that safety questions can be considered, there is no basis for the introduction of an artificial rule that the Administrator cannot take action to exclude a suspect chemical unless the proof shows definite past injury from it. If an ingredient may be excluded from a standard when proved harmful, why may not the Administrator find unfairness in exposing the public to a chemical that is closely related to known poisons and that has not yet been proved safe?

---

[20] It is also obvious that the power to fix standards was intended to supplement and implement the other provisions of the Act. Cf. the *Quaker Oats* decision at pp. 230-231. There is thus no merit in the argument by both Atlas (No. 610, Pet. 15, 17) and Glyco (No. 584, Pet. 21-24) that these regulations are invalid because they would allow the Administrator to avoid a judicial contest in which he would have the burden of proving that polyoxyethylene monostearate is a poisonous and deleterious substance, Sec. 402(a), 21 U.S.C. 342(a), or would make bread appear better or of greater value than it is, Sec. 402(b), 21 U.S.C. 342(b). The food standards provisions were intended by Congress as a means of maintaining the integrity of the food supply (H. Rep. No. 2139, 75th Cong., 3d Sess., 2 (1938)). The integrity from a toxicological standpoint is as important as economic integrity.

The language of the statute and ordinary common sense require that regulations not be issued which place the Administrator's stamp of approval on chemicals of doubtful safety proposed for addition to the most common staple in our diet, thus in effect making the public unwitting "guinea pigs."

In *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 227-228, 232, this Court held that a wholesome and beneficial ingredient could be excluded from the standard because of an indirect affect on public health arising from confusion in marketing. *A fortiori,* the statute permits the exclusion of suspect ingredients, the future effects of which are unknown.

As this Court pointed out in the *Quaker Oats* case (p. 228) "the exercise of the administrative rule-making power necessarily looks to the future." See also *American Airlines, et al.* v. *Civil Aeronautics Board,* 192 F. 2d 417, 421 (C.A.D.C.) where the court said:

> Since regulatory functions must necessarily contemplate the future, the law which is involved in those functions must be realistic enough to permit that scope. So, when a prospective rule is required to be upon evidence, that evidence must be construed to include estimates, or forecasts, or opinions, on future events. At the same time, governmental permissions for the future cannot be fashioned from pure fantasy, speculation devoid of factual premise. * * *

So long as the Administrator reasonably entertained a doubt as to the safety of the chemicals

when used in bread over a life span, he could not find that a regulation permitting their use would promote honesty and fair dealing in the interest of consumers.[21]

2. Atlas Powder Company's second point (No. 610, Pet. 20-22) is that the Court of Appeals upheld the Administrator's finding, through which he limited the use of mono- and diglycerides to not more than 20% of the shortening in bread to avoid deceptive softening effects (Atlas, R. 460-461), despite a total absence of evidence to support it.

An examination of the Court of Appeals' opinion reveals, however, that there was evidence to support the finding. Atlas interpreted this evidence one way. The Administrator interpreted it another (Atlas R. 3295). The court recognized that the proper interpretation of the evidence was arguable, but held that the Administrator was not arbitrary in placing his interpretation upon it (Atlas R. 3295).

This Court, in *Universal Camera Corp.* v. *National Labor Relations Board*, 340 U.S. 474, 491, and *National Labor Relations Board* v. *Pittsburgh S. S. Co.*, 340 U.S. 498, 502-503, has emphasized the finality of Court of Appeals' action in deter-

[21] Glyco makes a contention (No. 584, Pet. 24-25) that if the Administrator excludes an ingredient because the proof of its safety is inadequate, he must spell out in his findings of fact based on the record "a specific standard of adequacy." Clearly the Administrator was not required to explain on the record the fundamentals of the safety testing of chemicals proposed for use in foods. Cf. *Market Street Ry. Co.* v. *Railroad Commission*, 324 U.S. 548, 560-561. Here the Administrator has detailed the gross deficiencies in the proof of safety (Findings 41-42, Atlas R. 468-473). We respectfully submit that nothing more was required.

mining whether a finding is supported by substantial evidence. This Court does not make an "independent review of the review" below, and there is nothing here to indicate that the Court of Appeals either misapprehended or misapplied the *Universal Camera* rule. On the contrary, it is plain that the court conscientiously performed its review function.

Moreover, it is difficult to see how petitioner could be helped even if there were error, which we do not concede, in sustaining the finding. It would at best lead to the exclusion of mono- and diglycerides or reversal for the fixing of another limit on their use. It could not be used as a means to require the admission of polyoxyethylene monostearate into the standard. As the Court of Appeals pointed out, the many differences between mono- and diglycerides and polyoxyethylene monostearate justified their classification into separate groups (Atlas R. 3292-3293, 3294-3295).

3. The final contention made by Atlas (No. 610, Pet. 23-27) is that, contrary to the plain language of Section 701(f)(2), 21 U.S.C. 372(f)(2), the Court of Appeals abused its discretion in failing to make an independent determination whether the new evidence described in Atlas' motion for leave to adduce additional evidence [22] was material.

Despite a clear statement by Judge Hastie (Atlas

---

[22] The record contains no such motion. All offers of new evidence were made to the Administrator. Atlas complained that the Administrator abused his discretion in refusing to reopen the record.

R. 3298) that a *de novo* examination of the proffered evidence had been made, and had led the court to agree with the Administrator that it was insufficient to change the result and thus inadequate to require reopening, Atlas insists that the court made no such independent review.

The Atlas contention that the court should review *de novo* the Administrator's denial of the motion to reopen was an afterthought. In the petition for review (Atlas R. 3248-3249, para. 32-35), Atlas complained that the Administrator had acted unlawfully in refusing to reopen the record. After respondent placed reliance on *Interstate Commerce Commission* v. *Jersey City,* 322 U.S. 503, 514-519, urging that the question presented to the Court was whether the Administrator had abused his discretion, Atlas insisted it was entitled to a *de novo* review of the materiality of the new evidence. Though the Court of Appeals agreed that reopening is normally a matter for the Administrator's discretion—particularly where all of the alleged new evidence has been submitted to him and he has expressed his expert judgment that it is insufficient to change the result already reached on an extensive record—the court gave Atlas an independent review.

What Atlas is really contending is that the Court of Appeals erred when it accepted the Federal Security Administrator's statement that the Food and Drug Administration's experimental data was incomplete and thus indecisive on the safety issue. Atlas characterizes this statement, officially made

by a responsible government official, as a "hearsay representation of a party" (No. 610, Pet. 26).

It is respectfully submitted that the court below properly accepted the government official's statement as to the status of the alleged experimental work, without insisting that a group of scientific work sheets be certified to it for appraisal even before the scientists engaged in the experiments were ready to formulate conclusions on them. The latter course would have had the effect of enlarging the scope of judicial review, contrary to this Court's decision in *National Labor Relations Board* v. *Donnelly Garment Co.*, 330 U.S. 219, 233-237.

CONCLUSION

For the foregoing reasons, we respectfully submit that the petitions for writs of certiorari should be denied.

ROBERT L. STERN,
Acting Solicitor General.
WARREN OLNEY III,
Assistant Attorney General.
BEATRICE ROSENBERG,
Attorney.

WILLIAM W. GOODRICH,
Assistant General Counsel,
Federal Security Agency.
MARCH 1953.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1953 246030 1314

IN THE

Supreme Court of the United States

OCTOBER TERM, 1952

No. 610

ATLAS POWDER COMPANY, a Corporation, *Petitioner,*

v.

OSCAR R. EWING, Federal Security Administrator, *Respondent.*

On Petition For a Writ of Certiorari to The United States Court of Appeals For The Third Circuit

PETITIONER'S REPLY TO RESPONDENT'S BRIEF IN OPPOSITION

I.

Our petition raises the novel and important question whether the Congress intended to authorize the Federal Security Administrator to ban the use of an established food product on a negative finding that suitability had not been proven, rather than an affirmative finding of unsuitability.

The Administrator's statement of the questions presented is framed as if he did not act on a negative finding at all (Res. 2-3).* The Administrator's Brief attempts

* Our Petition for Certiorari is referred to as (Pet. —); Respondent's Brief in Opposition is referred to as (Res. —).

to create the impression that he affirmatively found "the gravest doubts" about the safety of Myrj 45 (Res. 21).

The short answer is that the Administrator's findings do not include any statement that he had "the gravest doubts" about the safety of Myrj 45. The Administrator's finding which is his own summary of the so-called affirmative evidence reads as follows:

> "Although the record shows no definite evidence of injury from the use of . . . polyoxyethylmonostearate in amounts in which they are likely to occur in the diet from their use in bread, the results of the pharmacological tests reported do not warrant the conclusion that there is no likelihood of injury from bread containing these substances in the amounts proposed to persons consuming it continuously over a life span." (R. 473).

This negative finding was the Administrator's ultimate description of the total factual situation and the conclusion which he drew from the facts. It represented the most that in his opinion the record permitted him to say about the safety of Myrj 45. The doubt-raising "affirmative findings" referred to by the Administrator's Brief (Res. 21) were merged into the ultimate finding, which was negative in form. The negative finding was not mere redundancy, nor was it an accident. The Administrator had been reviewing a record closed for almost three years. He had been reviewing exceptions to his tentative findings —which included a similar but somewhat different negative finding on safety*—for over a year and a half. In the light of this history, the cautiously worded negative finding cannot be interpreted as the equivalent of an affirmative finding of unsuitability on safety grounds,

---

* The tentative finding was: "Although there has been no definite evidence of injury from the use of . . . polyoxyethylene monostearate in amounts in which they are likely to occur in the diet from their use in bread, the investigational work does not definitely establish their safety, and the record does not permit a conclusion that bread containing them is safe for continuous use over the human life span." (R. 15).

i.e., that there is a "likelihood of injury". If the Administrator had thought the record showed a "likelihood" of injury, he would have so found.

Further proof that the Administrator did not think he could so find, and does not think so today, is contained in a speech delivered by the Honorable M. R. Stephens, Associate Commissioner of Food and Drugs, in Chicago on March 4, 1953, before the Society of Bakery Engineers. A copy of the Federal Security Agency's press release containing the full text of this speech has been filed with the Clerk of this Court. Mr. Stephens was discussing the bread standard, and the pending cases challenging the validity of the standards.* He then continued:

> "The adjudication of these cases should settle once and for all any question about the use of that chemical [polyoxyethylene monostearate] in the standardized breads. Th re exists no provision in the law however under which this chemical can be automatically excluded from unstandardized products. Even though we do not regard the evidence of safety as adequate, we cannot exclude it from the unstandardized products *until we can produce evidence to prove in Court that its use may be injurious to health.*" (p. 2, emphasis added).

Mr. Stephens' statement of the law as applied to unstandardized foods states our point exactly, as applied to standardized foods. We maintain that an established product cannot be excluded from a food standard on the issue of safety "until" the Administrator finds on "evidence" in the record at least as much as he would have to *prove* in a court action based on the substantive provisions of the Act relating to safety (Pet. 15-17). That is to say, he must

* In addition to No. 584 and No. 610, now pending before this Court, another manufacturer of polyoxyethylene monostearate, Research Products Co., has filed a petition for review of the Administrator's order in the Court of Appeals for the Eighth Circuit. Briefs have not yet been filed, but a Government motion to affirm is pending.

find at least "that its use may be injurious to health."* The Administrator could not make and did not make any such finding here.

To the extent that the Administrator admits having relied on a negative finding, he has chosen to meet our contention that he lacks power to do so by paraphrasing it into two different contentions, neither of which we made.

The Administrator first suggests we have argued that he has no authority to consider questions of safety in a food standard proceeding (Res. 22-23). We did not and do not so contend. The Administrator next suggests we have argued that a finding of definite past injury is essential to exclude an ingredient from a food standard (Res. 23). We did not and do not so contend. Our argument is simply that he acted on a negative finding; and it is the legality of that action which we contest.

The Administrator's reliance on *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218 (1943), does not solve his problem. His point is that because *Quaker Oats* approved exclusion of a concededly wholesome ingredient, exclusion of "suspect ingredients" is *a fortiori* within his power (Res. 24). If *Quaker Oats* had approved exclusion on a negative finding, the Administrator's point would be well taken. But exclusion there was based on an affirmative finding that the ingredient "would tend to confuse and mislead consumers" (318 U.S. 218, 223), not a negative finding that the evidence failed to prove the ingredient "would not tend to confuse and mislead consumers."**

---

* In this context, of course, "may" connotes probability, rather than possibility. *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 658 (1914). The phrase "may be injurious" is therefore equivalent to "likelihood of injury."

** The Administrator's only direct challenge to our demonstration that Congress did not intend and did not authorize the use of negative findings in food standard proceedings is to quote from a 1952 report of the House of Representatives Select Committee to Investigate the Use of Chemicals in Foods, written 14 years after the statute being construed was enacted in 1938. (Res. 22, n. 19).

The Administrator has made no attempt to disprove the great importance of the negative finding issue as a matter of general administrative law. In addition to the reasons which we have cited (Pet. 8-11), it has recently come to our attention that another administrative agency is currently making use of negative findings under circumstances in which their authority to do so may be questionable. In *United States ex rel. Dolenz* v. *Shaughnessy*, 200 F. 2d 288 (2 Cir., 1952), a divided Court of Appeals upheld an order dismissing a writ of habeas corpus brought by an alien whose deportation had been ordered. The Court held that the Attorney General's delegate did not abuse his discretion in ordering deportation on the ground that he did not find that the alien would be subjected to physical persecution if deported to Yugoslavia. Judge Charles E. Clark, dissenting, stated that ". . . the finding here in question is inadequate, since it is carefully negative in form." 200 F. 2d 288, 292. A Petition for Writ of Certiorari is pending before this Court (No. 576, October Term, 1952).

In the *Dolenz* case, the statute involved may conceivably be at least susceptible to interpretation as an explicit Congressional authorization of exclusion on the basis of a negative finding. In the instant case, the food standard section of the statute cannot be construed to authorize a negative finding explicitly and no such authorization can be implied in view of the contrasting language of the new drug provisions of the same statute as well as the pendency of proposed legislation designed to apply the new drug principle to food.

No matter how this statement may be interpreted, this Court has repeatedly refused to accept the opinion of members of a subsequent Congress about legislation enacted by a previous Congress "as authoritative guides to the construction of" that legislation. *United States* v. *United Mine Workers*, 330 U.S. 258, 281-282 (1947); *Fogarty* v. *United States*, 340 U.S. 8, 13-14 (1950). These precedents are particularly applicable to a Committee expression where, as here, no member of the Committee expressing the opinion was a member either of the Committee which drafted the legislation or even of the Congress which enacted it.

The essential unreviewability of negative findings poses a novel issue of administrative law which has far reaching implications. Whether a Congressional intent to cut down judicial review should be implied when Congress has not so directed expressly is a question which this Court should resolve.

II.

In our petition we also contended that the Court of Appeals had approved an important finding made entirely without supporting evidence (Pet. 20-22). The Administrator answers that an "examination of the Court of Appeals' opinion reveals, however, that there was evidence to support the finding." (Res. 25). However, the Administrator's brief makes no citation to any record evidence supporting his finding that a "non-deceptive" level of use existed for the mono- and diglycerides. As we have pointed out, there was no such evidence (Pet. 21). Furthermore, a careful analysis of the Court of Appeals' opinion on this point shows that the Court of Appeals did not and could not say that this finding was supported by substantial evidence (See Pet. 21-22). The Court of Appeals sustained the conclusion on the theory that it was an allowable exercise of administrative judgment (R. 3294-95)—a judgment unsupported by any facts (Pet. 20-22). This was clear error, which is not concealed by the Administrator's reference to the Court's opinion.

The Administrator further argues that if the Court of Appeals did commit error in this respect, we cannot complain of it because, he says, "[i]t could not be used as a means to require the admission of polyoxyethylene monostearate into the standard." (Res. 26).

This is hardly an answer. It was not the function of the Court to direct the Administrator to include our product in the standard. But, where agencies act without any supporting evidence and, in the process, formulate arbitrary discriminations, Courts have the duty to reverse for the

taking of corrective measures. In this case the corrective measure would be a determination by the Administrator whether, on the issue of deception, there is a basis (record evidence alone considered) to distinguish between our products and the competing mono- and diglycerides.

III.

We also argued in our petition that the Court of Appeals ignored prior decisions of this Court by failing to make an independent determination of the materiality of evidence which we sought to have adduced in a reopened hearing, pursuant to Section 701(f)(2) of the Act (Pet. 23-27). The Administrator concedes that all the Court of Appeals had before it on the question of the materiality of tests conducted by the Food and Drug Administration itself on our product was a statement in the Administrator's brief that such evidence was not material. The Administrator objects to our characterizing this as "a hearsay representation of a party" (Res. 27-28). We adhere to that characterization. If counsel for Atlas had told the Court of Appeals that Atlas possessed evidence proving beyond any doubt that its products were absolutely safe, and if the Court of Appeals, relying on this representation, had ordered the Administrator to reopen the hearings, the Administrator would be here today making the same complaint that we make and he would be entitled to the same relief to which we are entitled. The Government's *ipse dixit* is no more conclusive than anyone else's. Cf. *United States* v. *Packer*, 200 F. 2d 540, 542 (2 Cir., 1952), *cert. granted*, 21 U.S.L.W. 3244 (1953).

There is some suggestion by the Administrator that we never invoked the Court of Appeals' power under Section 701(f)(2) of the Act to order the production of additional evidence in a reopened hearing (Res. 26). This ignores both the prayer for relief in our Petition for Review (R. 3249-3251) and the assumption by the Court of Appeals that Section 701(f)(2) had been invoked (R. 3297-3298).

Conclusion

We respectfully renew our prayer that our petition be granted.

Oscar Cox,
1210 18th Street, N.W.,
Washington 6, D. C.,
Attorney for Petitioner.

C. C. Gammons,
Kenneth E. Mulford,
Roger R. Horton,
Delaware Trust Co. Bldg.,
Wilmington, Delaware.

Ezekiel G. Stoddard,
Lloyd N. Cutler,
Louis F. Oberdorfer,
Herbert L. Packer,
William R. Perlik,
1210 18th Street, N.W.,
Washington 6, D. C.
Of Counsel.